UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.* Case No: 1:03-cv-11226-PBS	)	**Judge Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

DEFENDANTS DEY, INC. AND DEY, L.P.'S LOCAL RULE 56.1 STATEMENT IN OPPOSITION TO PLAINTIFFS' STATEMENT OF ADDITIONAL UNDISPUTED FACTS IN OPPOSITION TO DEY'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Pursuant to Local Rule 56.1, defendants Dey, Inc., and Dey, L.P., (collectively, "Dey"), submit the following Rule 56.1 Statement in opposition to the Statement of Additional Undisputed Facts in Opposition to Defendants' Motions for Partial Summary Judgment, Dkt. No. 6790 (the "Additional Statements").

GENERAL RESPONSES AND OBJECTIONS

Dey generally objects to the Additional Statements insofar as they inappropriately conjoin completely unrelated or marginally related statements together as one purported factual statement. Dey generally objects to the Additional Statements insofar as they are immaterial to the issues before the Court on the present motion. Dey generally objects to the citation of evidence which does not support a particular fact or is not the best evidence of a particular fact. Dey's agreement that a fact is undisputed is not an agreement that Plaintiffs' citations support such fact and is limited to this motion only. Dey objects to the Additional Statements to the extent that the purported "undisputed facts" contained therein are supported by testimony elicited

from a witness produced by California through leading questions asked by California's counsel during direct examination.

SPECIFIC RESPONSES

1. Dey never contacted Medi-Cal after OIG issued its 1996 report "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services." (Hanscom Decl. Ex. 21 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 303:3-18.)

RESPONSE

Dey objects to the testimony cited in paragraph 1 as violative of Rule 611(c) of the Federal Rules of Evidence, on the grounds that it was elicited from a witness produced by California through leading questions asked by California's counsel during direct examination. To the extent a response is required, Dey disputes paragraph 1 on the grounds that it is not supported by the evidence cited therein. In the testimony cited in paragraph 1, Mr. Rosenstein testified that, to his knowledge, no manufacturer came to the program "to offer help in reforming its reporting of AWPs" or to "express[] any concern about the implications of that report." Moreover, Dey states that it did contact Medi-Cal after the publication of the 1996 OIG report concerning its reporting of AWP. Starting in 1999, Dey sent price notification letters to Medi-Cal administrators explaining that its AWPs did not reflect prices charged or paid in the marketplace, that it was Dey's practice to set its AWP before any drugs were sold and not to subsequently change it, and Dey understood that its pricing practices were consistent with industry practice. (Dey SOF at ¶¶ 28-29, 31-33, 35.[1]) The letters invited Medi-Cal officials to contact Dey if they had any questions, but no Medi-Cal officials ever contacted Dey or investigated the matters contained in the letter. (Dey SOF at ¶¶ 34, 36.)

[1] "Dey SOF at ¶ __" refers to the Statement of Undisputed Material Facts in Support of Dey, Inc. and Dey, L.P.'s Motion for Partial Summary Judgment, Dkt. No. 6695.

2. Accurate AWPs would have given Medi-Cal an accurate reimbursement system which would have saved the taxpayers hundreds of millions of dollars. (Hanscom Decl. Ex. 21 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 303:19-304:11, 313:19-314:3.)

RESPONSE

Dey objects to the testimony cited in paragraph 2 as violative of Rule 611(c) of the Federal Rules of Evidence, on the grounds that it was elicited from a witness produced by California through leading questions asked by California's counsel during direct examination. Dey further objects to the reference to "hundreds of millions of dollars" as immaterial, irrelevant, and unduly prejudicial on the grounds that California's damages estimates as to Dey do not reach "hundreds of millions of dollars." To the extent a response is required, Dey disputes paragraph 2. The reimbursement payments that are at issue in this action are not "overpayments" and were not caused by Dey. Rather, they were the direct result of deliberate and informed decisions by California to pay providers more than their actual acquisition costs for drugs to achieve its own policy goals. (*See* Joint SOF at ¶¶ 24-26, 33, 35-40, 52-53, 55, 67.[2]) Moreover, considering that California has never defined AWP as anything other than a price listed in compendia, Dey could never have reported "inflated" or "incorrect" AWPs. (*See* Joint SOF at ¶ 20.)

3. Dey has never given anyone in the California Legislature an explanation of the difference between provider costs and AWPs on Dey's drugs. (Hanscom Decl. Ex. 21 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 308:2-309:1.)

RESPONSE

Dey objects to the use of the testimony cited in paragraph 3 as violative of Rule 611(c) of the Federal Rules of Evidence, on the grounds that it was elicited from a witness produced by California through leading questions asked by California's counsel during direct

[2] "Joint SOF at ¶ __" refers to the Defendants' Joint Statement of Undisputed Material Facts in Support of Their Motions for Partial Summary Judgment, Dkt. No. 6703.

examination. Dey further objects to the testimony cited in paragraph 3 as immaterial and irrelevant. California has understood since at least the late 1970s that compendia AWPs significantly exceed providers' actual costs to acquire prescription drugs. (*See* Joint SOF at ¶¶ 22-41.) Despite this understanding, California has never defined AWP in a statute or regulation as anything other than a price listed in compendia, and has never offered any guidance as to how AWP should be determined. (*See* Joint SOF at ¶ 20.) Moreover, the California legislature has twice deliberately enacted statutes calling for reimbursement based in part on compendia AWP, knowing full well that the resulting payments would exceed providers' acquisition costs, especially for generic drugs. (*See* Joint SOF at ¶¶ 52-53, 55, 67.)

4. Dey has never provided DHCS with any information stating the difference between Dey's AWPs and provider's actual acquisition costs. (Hanscom Decl. Ex. 22 (9/23/08 Hillblom Dep.) at 348:15-349-11.)

RESPONSE

Dey objects to the testimony cited in paragraph 4 as violative of Rule 611(c) of the Federal Rules of Evidence, on the grounds that it was elicited from a witness produced by California through leading questions asked by California's counsel during direct examination. To the extent a response is required, Dey disputes paragraph 4. Dey states that it did contact Medi-Cal after the publication of the 1996 OIG report concerning its reporting of AWP. Starting in 1999, Dey sent price notification letters to Medi-Cal administrators explaining that its AWPs did not reflect prices charged or paid in the marketplace, that it was Dey's practice to set its AWP before any drugs were sold and not to subsequently change it, and Dey understood that its pricing practices were consistent with industry practice. (Dey SOF at ¶¶ 28-29, 31-33, 35.) The letters invited Medi-Cal officials to contact Dey if they had any questions, but no Medi-Cal

officials ever contacted Dey or investigated the matters contained in the letter. (Dey SOF at ¶¶ 34, 36.)

5. No one in the California Legislature has ever accepted or approved any inflated or false AWPs. (Hanscom Decl. Ex. 21 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 308:2-309:1.)

RESPONSE

Dey objects to the use of the testimony cited in paragraph 5 as violative of Rule 611(c) of the Federal Rules of Evidence, on the grounds that it was elicited from a witness produced by California through leading questions asked by California's counsel during direct examination. Dey further objects to the testimony cited in paragraph 5 as immaterial and irrelevant. To the extent a response is required, Dey disputes paragraph 5. California has understood since at least the late 1970s that compendia AWPs significantly exceed providers' actual costs to acquire prescription drugs. (*See* Joint SOF at ¶¶ 22-41.) Despite this understanding, California has never defined AWP in a statute or regulation as anything other than a price listed in compendia, and has never offered any guidance as to how AWP should be determined. (*See* Joint SOF at ¶ 20.) Therefore, there is no basis to contend that Defendants reported "inflated" or "false" AWPs. Moreover, the California legislature has twice deliberately enacted statutes calling for reimbursement based in part on compendia AWP, knowing full well that the resulting payments would exceed providers' acquisition costs, especially for generic drugs. (*See* Joint SOF at ¶¶ 52-53, 55, 67.)

6. It was never the policy of DHCS to accept false information. (Hanscom Decl. Ex. 21 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 315:3-5.)

RESPONSE

Dey objects to the use of the testimony cited in paragraph 6 as violative of Rule 611(c) of the Federal Rules of Evidence, on the grounds that it was elicited from a witness produced by California through leading questions asked by California's counsel during direct examination. To the extent a response is required, Dey disputes paragraph 6. California has understood since at least the late 1970s that compendia AWPs significantly exceed providers' actual costs to acquire prescription drugs. (*See* Joint SOF at ¶¶ 22-41.) Despite this understanding, California has never defined AWP in a statute or regulation as anything other than a price listed in compendia, and has never offered any guidance as to how AWP should be determined. (*See* Joint SOF at ¶ 20.) Therefore, there is no basis to contend that Dey reported "false" prices or "false information." Moreover, California deliberately adopted a reimbursement methodology, based in part on compendia AWPs, that it knew would pay providers more than their actual acquisition costs for drugs to achieve its own policy goals, including compensating providers for inadequate dispensing fees. (*See* Joint SOF at ¶¶ 24-26, 33, 35-40, 52-53, 55, 67.)

7. It was not the policy of DHCS to over-reimburse. (Hanscom Decl. Ex. 23 (3/19/08 Gorospe Dep.) at 357:16-19, 384:8-13; Hanscom Decl. Ex. 14, (5/6/09 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 610:19-611:5.)

RESPONSE

Dey objects to the use of the testimony cited in paragraph 7 as violative of Rule 611(c) of the Federal Rules of Evidence, on the grounds that it was elicited from a witness produced by California through leading questions asked by California's counsel during direct examination. To the extent a response is required, Dey disputes paragraph 7. California has understood since at least the late 1970s that compendia AWPs significantly exceed providers'

actual costs to acquire prescription drugs. (*See* Joint SOF at ¶¶ 22-41.) Nonetheless, California deliberately adopted a reimbursement methodology, based in part on compendia AWPs, that it knew would pay providers more than their actual acquisition costs for drugs to achieve its own policy goals, including compensating providers for inadequate dispensing fees. (*See* Joint SOF at ¶¶ 24-26, 33, 35-40, 52-53, 55, 67.) Dey, therefore, objects to this statement on the grounds that it is irrelevant and immaterial because there is no evidence in the record that California "over-reimbursed" for any of the Dey Subject Drugs.

8. In 1999, the California Legislature ordered a study of the reimbursement problem. (Hanscom Decl. Ex. 18 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 237:21 -239:16.)

RESPONSE

Dey does not dispute that the California legislature ordered a study of Medi-Cal pharmacy reimbursement rates in 1999 but disputes that there was a "reimbursement problem" at the time. The cited testimony does not support the assertion that there was a "reimbursement problem." Moreover, the evidence in the record indicates that California deliberately chose the reimbursement methodologies it adopted during the relevant time period, knowing that they would pay providers more than their actual acquisition costs for drugs, to achieve its own policy goals. (*See* Joint SOF at ¶¶ 24-26, 33, 35-40, 52-53, 55, 67.)

9. The Myers & Stauffer report took approximately 18 months to complete. The Myers & Stauffer report, received on August 23, 2002, was received too late for the California legislature to use for any legislation in 2002. It was used to some extent in 2004 legislation. (Hanscom Decl. Ex. 18 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 246:8–247:1.)

RESPONSE

Dey does not dispute the first and third sentences of paragraph 9. Dey does not dispute that the cited testimony of Dr. Gorospe supports the second sentence of paragraph 9, but

objects to the cited testimony as irrelevant and immaterial. By the time California adopted AWP minus ten percent, it was well aware that providers could acquire generic drugs at prices significantly below AWP, regardless of whether it had an opportunity to review the Myers and Stauffer report. In the enrolled bill report recommending that the Governor sign AB 442 into law, the California Department of Health Services acknowledged that providers could acquire generic drugs at 40 to 50 percent below compendia AWP, but noted that it dropped a proposal to reimburse for generic drugs at AWP minus 40 percent out of concerns that the reductions would create access problems for Medi-Cal beneficiaries. (*See* Joint SOF at ¶ 52.)

10. The Medi-Cal program depends on the honesty of the people who participate in the program. (Hanscom Decl. Ex. 21 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 309:14-20.)

RESPONSE

Dey objects to the use of the testimony cited in paragraph 10 as violative of Rule 611(c) of the Federal Rules of Evidence, on the grounds that it was elicited from a witness produced by California through leading questions asked by California's counsel during direct examination. To the extent a response is required, Dey disputes paragraph 10. California has understood since at least the late 1970s that compendia AWPs significantly exceed providers' actual costs to acquire prescription drugs. (*See* Joint SOF at ¶¶ 22-41.) Despite this understanding, California has never defined AWP in a statute or regulation as anything other than a price listed in compendia, and has never offered any guidance as to how AWP should be determined. (*See* Joint SOF at ¶ 20.)

11. California's open formulary contains over 26,000 NDCs. (Hanscom Decl. Ex. 14 (5/6/09 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 619:17-620:2.)

RESPONSE

Dey objects to the cited testimony as irrelevant and immaterial.

Dated: January 15, 2010

KELLEY DRYE & WARREN LLP

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on January 15, 2010, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
Sarah L. Reid